



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/772,704

02/05/2004

George C. Tsokos

Army 178

5604

30951

7590

12/12/2008

NASH & TITUS, LLC

21402 UNISON RD

MIDDLEBURG, VA 20117

EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

12/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/772,704	Applicant(s) TSOKOS ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,10,11,15,29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,10,11,15,29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 08/18/2008 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 04/14/2008 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 10-11, 15 and 29-30 are pending and currently under examination in the current application.

Response to Applicant's Arguments

Re: Claim Rejections - 35 USC § 103

Applicant's arguments filed 08/18/2008 have been fully considered but they are not persuasive. Applicant argues that Solomou et al. was a paper written by the present inventor and reports the discovery of CREM as being the culprit for decreased IL-2 production however this was early work and it was not known at the time how to alleviate or resolve the problem. Applicant next argues against Weintraub, Monia et al., Symonds et al. and Gruenberg et al. individually and concludes that although a person of ordinary skill in the art would have appreciated from Solomou et al that it was desirable to increase IL-2 production in SLE patients and that CREM causes decreased

Art Unit: 1635

IL-2 production, neither it or the cited references provide any guidance to the skilled artisan on how to modify T cells with antisense CREM in such a way that they would actually increase IL-2 production.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Given that Solomou et al teach that it was desirable to increase IL-2 production in SLE patients and that CREM causes decreased IL-2 production, a person of ordinary skill in the art, upon reading Solomou et al., would have recognized the desirability of increasing IL-2 production by inhibition of expression of the suppressor protein CREM in SLE patients. It was well known in the art at the time of filing of the instant invention that using antisense compounds were an efficient method of inhibiting unwanted protein expression for any gene and therefore one of ordinary skill in the art would have looked to both Weintraub and Monia et al. who teach known methods of inhibiting expression of a target gene using antisense molecules. It would have been a matter of routine experimentation to design an antisense compound targeted to a gene encoding CREM and because Monia et al. is considered to comprise detailed instructions on using antisense compounds to inhibit gene expression for the purpose of providing treatment effects, it would have been obvious one of ordinary skill in the art to try the methods

Art Unit: 1635

taught by Weintraub and Monia et al. to decrease the expression of CREM protein in an effort to increase the production of IL-2 in SLE patients.

Furthermore, because it is taught in the prior art how to inhibit expression from any target gene and it was known in the prior art that inhibition of the expression of the IL-2 suppressor increases IL-2 production in T cells of SLE patients, which have been taught to have therapeutic effects SLE patients, it would have been obvious to genetically modify T cells, as taught by Grueberg et al. and Symonds et al. to inhibit CREM expression in an effort increase IL-2 production in SLE patients.

Applicant argues Symonds et al. proposes transfection of CD34 progenitor cells and not terminally differentiated cells. However it must be pointed out to Applicant that the claims are drawn broadly to any T-cell and not specifically terminally differentiated cells are argued. Applicant further argues Gruenberg et al. operates without any growth factors unlike the present invention and argue the methods of Gruenberg et al. are unpredictable and illustrates the difficult in working with genetic mechanisms in T cells. . Again, the instant claims do not require the use of any growth factors as argued and the methods taught by Gruenberg et al. would have reasonably been expected to be applicable to a method of increasing IL-2 in SLE patients and it would have been a matter of routine experimentation to use the methods taught by Gruenberg et al. to perform the methods instantly claimed.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service

Art Unit: 1635

center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Examiner
Art Unit 1635